A. Requirements for Submissions

We are seeking innovative proposals from organizations that can test whether models of disease management improve clinical outcomes and appropriate use of Medicare-covered services for targeted Medicare fee-for-service beneficiaries, while managing Medicare expenditures under Parts A and B to achieve reduced aggregate Medicare expenditures.

Models that are targeted specifically at the Medicare population and that take into account the beneficiaries' relative health and functional status, age, mental functioning, and other relevant factors, are of particular interest. Preference will be given to proposals that focus on beneficiaries most likely to benefit from disease management interventions and that take patient co-morbidities into account in the services provided. In selecting applicants for this demonstration project, we will also consider whether the applicant will serve the Medicare ethnic patient populations disproportionately affected by the targeted diseases.

At a minimum, applicants must explain how their proposed program addresses each of the following aspects of the demonstration:

1. Targeting the Appropriate Population

    a. Identifying Eligible Medicare Beneficiaries

        Beneficiary participation in this demonstration is strictly voluntary. Each beneficiary must be fully informed about the demonstration and must sign an informed consent form in order to participate. In addition to indicating informed consent, Medicare beneficiaries must satisfy the following conditions in order to be able to participate in the DM Demonstration project:

        Eligibility Criteria:

- Must be a Medicare beneficiary enrolled in Part A and B
- Medicare must be primary payer
- Must have chronic, advanced-stage CHF, diabetes, and/or coronary heart disease (see "Suggested Disease Identification Guidelines" section for additional information on identifying the appropriate intensity and severity of targeted diseases)
- Must have his or her physician's approval of participation in the project

        Medicare beneficiaries will be excluded from eligibility if they:

- are currently enrolled in a Medicare+Choice plan
- are receiving hospice or ESRD benefits
- are currently participating in another CMS demonstration
- have resided in any institution for more than one hundred days over the past twelve months
- are unable to participate in self-care activities due to severe dementia or other serious mental illness
- are terminally ill Medicare beneficiaries with likely survival of less than three months

Applicants must state clearly any additional inclusion or exclusion criteria it plans to use, as well as the reasons why the additions are needed.

Applicants must explain in detail the processes by which participant identification, recruitment, randomization, selection, enrollment, and discharge from the program will occur, including how drop-out rates will be monitored and mitigated. Applicants must explicitly state how their referral sources will use common or readily available information, tests, or instruments to properly identify appropriate candidates before enrollment in order to reduce the incidence of post-enrollment beneficiary rejection due to ineligibility. CMS expects that each DM organization will treat at least 5,000 Medicare beneficiaries over the course of the project. Applicants must specify how many beneficiaries they expect to treat each year at each site.

b. Identifying Chronic, Advanced-Stage CHF, Diabetes, and/or Coronary Heart Disease

The following guidelines are provided to assist applicants in identifying the appropriate intensity and severity of diseases targeted for this project. These guidelines were specifically developed for the purpose of this demonstration project and are in no way to be considered all-inclusive. Certain elements have been adapted or adopted from published studies (references available upon request).

Applicants are not required to use these specific guidelines; however, if an applicant chooses not to use them, it must detail the disease identification guidelines it proposes using and explain why alternative guidelines are preferred.

Suggested Disease Identification Guidelines

Congestive Heart Failure

1. Previous inpatient or outpatient diagnosis of heart failure (pulmonary congestion on x-ray; or typical signs and symptoms and improvement after diuresis; or ICD-9-CM codes 402.01, 402.11, 402.91, 404.01, 404.11, 404.91, 428.x)

AND

One or more of the following:

1. Hospitalized in an acute care hospital with a principal diagnosis of heart failure within the past year
2. New York Heart Association functional status class II, III, or IV (at the time of enrollment or within the prior 30 days)

Diabetes

1. Current diagnosis of Type 1 or Type 2 diabetes mellitus
2. Treatment with insulin or oral hypoglycemic medication(s)

AND

3. One or more of the following:
    a. Cardiovascular disease (ischemic heart disease, hypertension, cerebrovascular disease)
    b. Renal disease (kidney replacement, end-stage renal disease (ONLY if not already receiving benefits for ESRD), renal failure, proteinuria)
    c. Eye disease (blindness, glaucoma, cataract, vitreous hemorrhage, detached retina, retinopathy)
    d. Lower extremity disease (amputation, ulcer, musculoskeletal deformity, peripheral vascular disease, neuropathy)
    e. HbA1C >9.5% within the past year
    f. Hospitalization for a principal diagnosis of diabetes and metabolic decompensation (e.g., ketoacidosis or hyperglycemia/hyperosmolarity) within the past year
    g. Self-reported health status as "fair" or "poor" (at the time of enrollment or within the prior 30 days)

Coronary Heart Disease

1. One or more of the following indicators of coronary artery disease
    a. Previous percutaneous coronary intervention (coronary angioplasty with or without stent, or coronary atherectomy) or coronary artery bypass surgery
    b. Previous myocardial infarction (documented clinical evidence of myocardial damage; or previous hospitalization with a principal diagnosis of ICD-9-CM code 410.xx)
    c. Current diagnosis of angina and prescribed one or more anti-anginal medications in addition to as needed (PRN) sublingual nitroglycerin (Note: if anginal symptoms are controlled by the medication[s], the patient is still eligible for enrollment)

AND

2. One or more of the following:
    a. Congestive heart failure
    b. Diabetes
    c. Hospitalization for any reason within the past year
    d. Self-reported health status as "fair" or "poor" (at the time of enrollment or within the

prior 30 days)

2. Description of Disease Management Intervention Services

Applicants must be able to serve a chronically ill Medicare population as defined by their targeting protocols mentioned above. The proposed disease management services must be appropriate for the targeted population, and must be likely to improve the quality of care for these individuals. Applicants' proposals must show adequate mechanisms for ensuring the medical necessity and reasonableness of the disease management services furnished under the demonstration.

Applicants must also have a defined scope of evidence-based and guideline-recommended disease management services that are to be provided over a defined service period.

Applicants must specify the pharmacy intervention and protocols to be followed as well as the pharmacy distribution network to be used during the demonstration.

In addition, applicants must address how they will ensure that beneficiaries' physicians are integrated into the project. The intervention must also include how the applicant will ensure optimal medical management; enhance and support patient self-management and patient and caregiver education; ensure efficient and effective utilization of Medicare services; and ensure adequate flow of patient information from setting to setting.

Proposals must address issues related to the utilization and cost of the medications or services, implications for the applicants' protocols, and other pertinent details. In particular, applicants need to provide detail on exactly how each service will be provided, whether by applicants' direct staff or contractual arrangements. If services will be provided by staff, applicants should describe the type and level of staff that will be providing the service, the proposed level of effort required, and a discussion of any special equipment, such as monitoring or electronic input devices. Similar detail is required for any services provided by other parties under contractual arrangements. Applicants should include detailed information, as well as copies of all materials, on all proposed educational or life style modification programs. The data to be collected, data sources, and data analyses planned must be specified in detail and must be sufficient to ensure optimal medical management and efficient use of health care services.

3. Organizational Capabilities

Applicants must demonstrate that they have the infrastructure to carry out the demonstration. At a minimum, the applicant must describe each of the following aspects in detail, also addressing their adequacy and availability:

- facilities

- equipment
- trained staff
- clinical protocols to guide care delivery and management
- linkages to providers and services necessary to deliver care
- appropriate information and financial systems

Accordingly, applicants must describe their experience in coordinating care, particularly for any chronically ill populations over 65, if possible. Proposals must include a detailed implementation plan describing tasks and timelines associated with implementing the demonstration program. Since applicants must demonstrate prior experience in operating successful disease management programs, the implementation plan should focus on tasks and a timeline for modifying the existing system, if necessary, to fit the features required for this demonstration. Applicants may need to modify their own disease management models, including protocols, services, outreach, and education initiatives to address a Medicare fee-for-service population, and if so, applicants must describe in detail what will need to be changed and why. Specific information should be provided concerning how the personnel are to be organized in the project and to whom they will report. The implementation plan must also describe how the organization will modify its existing data and claims systems in order to submit electronic claims and prescription drug information for payment to the appropriate Medicare contractor(s), using standard claims formats, and to meet all data requirements for the project. The pre-implementation start-up phase should not exceed six months from notice of grant award.

Demonstration projects will be required to cooperate in an independent formal evaluation of the demonstration, including submission of cost and other program data and site visits, conducted by CMS and/or its contractor. No additional funding will be provided for these activities.

<u>Using Proprietary Algorithms for Targeting and Treating Patients</u>
Preference will be given to proposals in which the intervention protocols are not proprietary in nature. If proprietary targeting and treatment protocols are proposed, a project award will be contingent upon the applicant's agreement to the following condition: "At any phase in the project, including at the project's conclusion, the awardee if so requested by the project officer, must deliver to CMS materials, systems, or other items applied, developed, refined or enhanced in the course of or under the award to be used to further the purpose of this demonstration project. These materials, systems, or other items shall not be subject to use for any other purpose."

4. Effectiveness of Intervention(s): Quality

Applicants must describe how their program will be effective in improving health status. For existing programs, applicants must show evidence of positive outcomes from prior and current efforts. Claims of prior success must include definitions of the outcomes measures used, as well as explanations of the length of time over which

they were measured and how the measures were calculated. Results from similar projects should be cited. For new programs, applicants must describe how their proposed intervention(s) is likely to have a positive effect. Applicants should be able to qualify and quantify their results through common or readily available measurements, or explain why and how an alternate measurement needs to be conducted to show improvement.

For each condition proposed, applicants must collect data that will be used to measure and demonstrate the effect of its intervention's outcomes. Below is a preliminary list of data CMS believes sites should collect during this demonstration.

Guidelines for Quality of Care/Outcomes Measurement for this Demonstration

The applicant will be expected to perform the measurements itself, as part of an ongoing quality improvement program. Specifically, the applicant will be expected to report at least one measure for each clinical topic (heart failure, diabetes, and/or coronary heart disease) targeted by its disease management program. Applicants targeting only one clinical topic should report at least two measures for that topic. Measurement before and after initiation of the intervention should be reported. The applicant should choose measures from among the ones asterisked below, and should describe its capacity for sampling and data collection in the proposal. Applicants will be expected to coordinate with the project officer and the consortium of awardee sites to standardize methodology as much as possible across demonstration sites.

Heart Failure

1. * Assessment of left ventricular ejection fraction
2. * Use of angiotensin converting enzyme inhibitors (ACEI)
3. Dose of ACEI

Diabetes

1. * Eye exam
2. * Lipid profile performed
3. * Lipids controlled (LDL<130 mg/dl)
4. * Hemoglobin A1c (HbA1c)
5. * Poor HbA1c control (>9.5%)
6. Monitoring for diabetic nephropathy
7. * Blood pressure controlled (<140/90)
8. Foot exam performed

Coronary Artery Disease

1. * Beta-blocker after acute myocardial infarction
2. * Cholesterol measurement and control
3. * Use of Aspirin
4. * Blood pressure control in patients with a concomitant diagnosis of hypertension

* May be chosen by demonstration site to fulfill quality of care reporting requirement

Sites selected for award will convene with CMS and an evaluation contractor to develop the specific data to be collected across sites for each disease category, as well as the standards to ensure consistent measurement strategies across sites.

5. Payment for Disease Management Services, Reduction of Medicare Expenditures, and Reinsurance

Payment for Disease Management Services

Using a monthly all-inclusive rate, applicants must propose an overall payment methodology and project budget that are appropriate for their proposed disease management delivery model and reduce aggregate Medicare program expenditures. Medicare Part A and B services will continue to be paid under the regular fee-for-service system (except as noted in Reinsurance a (ii) below).

a. All-Inclusive Rate - The applicant's payment methodology must propose an all-inclusive rate per enrolled beneficiary served per calendar month for the proposed bundle of disease management services. Enrollment begins the first day of the month following consent for participation from the beneficiary. This rate may be flat or stratified based on the intensity of services needed by a beneficiary. The monthly all-inclusive rate for disease management services furnished to participating beneficiaries will be considered an administrative fee, and except for "modest" cost-sharing relating only to the prescription drug benefit, no beneficiary coinsurance amount or deductible liability will be applied.

   i) The proposed payment amount must be reasonable given the scope of disease management proposed and must be supported by evidence of cost savings.

   ii) The proposed rate may include services other than disease management and/or payment(s) to subcontracted or other providers as long as the payments are tied to services furnished to an enrolled beneficiary and are not based upon referrals to the program.

   iii) Regardless of whether a fixed or variable rate is proposed, applicants must show how the services will serve beneficiaries, and, in detail, how its monthly rate was calculated based on its constituent components. At a minimum, the monthly rate should be broken into the following categories for each designated condition:

1. Disease Management Services provided by staff or under contract:
2. Prescription drug costs
3. Equipment (if applicable)
4. Physician services to be paid through demonstration
5. Other services (e.g., transportation)
6. Administrative Costs

All administrative costs relating to the demonstration should be included in this budget, including costs for: recruitment, travel, capital

investments, data collection, or any other costs incurred by the applicant in the provision of the proposed disease management services. No start-up funding will be available.

iv) Applicants should be aware that our primary interest is in testing the effectiveness of an all-inclusive rate payment and that this will be the primary basis for evaluating proposals. Performance-based financial incentive fee payments will not be offered.

b. Billing - Under the demonstration, the disease management entity may bill for and be paid for each calendar month for which the beneficiary was enrolled in the disease management program and received disease management service furnished by that disease management organization. Enrollment begins the first day of the month following consent for participation from the beneficiary. The selected demonstration sites must submit its bills for disease management services on an assignment basis. No balance billing will be permitted.

Reduction of Medicare Expenditures

Applicants must demonstrate that total payment under the demonstration will be less than what Medicare payment for the demonstration's enrollees would have been absent the demonstration. The applicant must estimate the expected total yearly Medicare expenditures for the projected enrolled population with and without the demonstration, and the resulting net savings to Medicare. Estimates of expenditures with the demonstration should include payment for disease management, pharmacy, and other demonstration services as well as the costs of the traditional Medicare services to the enrolled beneficiaries. Estimates of the cost of the traditional Medicare should reflect any expected changes in utilization and costs under the demonstration.

Applicants must show the basis for the assumptions used in their proposed payment methodology and project budget. Applicants' accuracy in and the strength of the evidence supporting these estimates will be considered in evaluating the proposals. Further, applicants selected for award will be required to submit data supporting their utilization and financial assumptions prior to award of waivers.

CMS or its contractor will use the information provided by the applicant as well as Medicare claims and other data to determine a waiver cost estimate, i.e. an estimate of what CMS would have to pay to provide care for a population similar to the projected enrolled population absent the demonstration.

Reinsurance

In accordance with the authorizing legislation, the disease management entity must guarantee, through an appropriate arrangement with a reinsurance company or otherwise that the demonstration will result in a net reduction in Medicare expenditures for the enrolled population. Each applicant will be required to show evidence that it can guarantee its estimated net reduction in aggregate Medicare

spending. Applicants will be required to establish a system to compensate Medicare in the event actual payments for Medicare services (including all DM payment costs and prescription drugs) exceed the estimate of what Medicare would have paid absent the demonstration.

a. Possible Reinsurance Approaches

Applicants may use one of the reinsurance approaches described below, or they may propose their own method as long as their reinsurance equivalent plan meets all of the criteria stipulated in the preceding paragraph.

i) The applicant may secure a valid reinsurance policy or post a bond of sufficient amount to guarantee a net reduction in aggregate Medicare payments. At the end of the demonstration, a final determination of the cost effectiveness of the demonstration will be based on a comparison of the total Medicare cost of the enrolled population (including traditional Medicare services and waivered services) to the total Medicare cost of the control group. This comparison will be part of an independent evaluation performed by a contractor funded by CMS. If the total cost of the enrolled population cost is greater than that of the control group, the disease management organization will be required to use its reinsurance policy or bond to reimburse CMS for the difference in costs. CMS may conduct interim reviews of expenditures to assure that the amount of the reinsurance policy or bond is sufficient to cover any overpayments. If these interim reviews reveal that the amount of the reinsurance policy or bond is insufficient, CMS will require the DM organization to increase the insured amount or bond accordingly.

ii) The applicant may choose to accept the waiver cost estimate as a cap on CMS' total financial liability for the demonstration. The applicant will have an opportunity to review the estimate and must agree in writing that the estimate will set the maximum CMS will expend for the enrolled population. CMS, in conjunction with the DM organization, will monitor Medicare expenditures for the enrolled populations (including traditional Medicare services and waivered services) using Medicare administrative claims records and payments to the DM organization and calculate aggregate totals on a regular basis to ensure program savings are achieved. If these calculations project that this cap will be reached during the demonstration period, Medicare's liability for the waivered demonstration services (disease management services and outpatient drugs) will end at the projected point in time, and the DM entity will be responsible for covering the costs of the waivered demonstration services for the remainder of the demonstration period. CMS will continue to process claims for traditional Medicare services throughout the demonstration period.

iii) An applicant may propose accepting full risk for the total package of Medicare covered services, similar to an at-risk Medicare+Choice plan. The applicant

would be paid a monthly capitation rate for each enrolled Medicare beneficiary based on the risk-adjusted Medicare+Choice payment methodology. The capitation rate will be set to achieve program savings. Under this method, no separate or additional payments would be made for the disease management demonstration services. The applicant would be required to provide all Medicare-covered services in addition to the disease management services either directly or through contractual arrangements with other Medicare certified providers. The applicant would be responsible for the costs of all Medicare-covered services whether provided by the applicant or another Medicare provider. Medicare beneficiaries enrolling in these plans will be informed that they are enrolling in a plan similar to a Medicare+Choice plan and are required to receive Medicare services through the plan.

b. Final Determination of Payment Methodology and Reinsurance

To insure that the total Medicare costs of the enrolled population do not exceed what would have been paid absent the demonstration, CMS will make the final determination of the payment method and reinsurance arrangements. The methodology selected for the reinsurance provision must be simple to administer while assuring that Medicare cost will not increase because of the demonstration.